Atty. Docket No. MSE #2620

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Gary E. Rehm		
Serial No.:	10/056,623	Group Art Unit:	1743
Filed:	01/28/2002	Examiner:	Ramillano, Lore Janet
Title:	Method and Apparatus for Using Infrared Readings to Detect Misidentification of a Diagnostic Test Strip in a Reflectance Spectrometer		

To: Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE AND AMENDMENT UNDER 37 CFR §1.121

Dear Sir or Madam:

This paper is filed in response to the Office Action mailed May 16, 2007. A response is due by August 16, 2007. This response is being filed on or before August 16, 2007, and is therefore timely filed.

Amendments

Please amend the above-identified U.S. application as follows:

In The Claims

Kindly enter the claim amendments, without prejudice, as set forth below. A complete listing of the claims is provided, with a parenthetical indication of the status of each claim, and markings to show current changes.

1. (currently amended) A method of using an infrared reading to detect the misidentification of a diagnostic test strip, said method comprising the step of:

determining if the infrared reflectance of one or more reagents are within an acceptable predetermined range; and

determining that the test strip is misidentified in the event the one or more reagents are outside of the acceptable predetermined range.

2. (original) The method of Claim 1, further comprising the step of aborting the test if said infrared reflectances are not within said range.

3. (original) The method of Claim 1 wherein said reagents are leukocyte, glucose and albumin.

4. (original) The method of Claim 3 wherein said predetermined infrared reflectance range of said leukocyte reagent is from about 57.0 to about 73.0 percent infrared reflectance.

5. (original) The method of claim 3 wherein predetermined infrared reflectance range of said glucose reagent is from about 75.0 to about 90.0 percent infrared reflectance.

6. (original) The method of claim 3 wherein the predetermined range of said albumin reagent is from about 60.0 to about 75.0 percent infrared reflectance.

7. (original) The method of Claim 2 wherein said test will be aborted if said test strip is more than about 0.020" from a central location on a feed table or if said test strip is incompletely

inserted by more than about 0.050".

8. (currently amended) An automated method of using an infrared reading to detect the misidentification of a diagnostic test strip disposed on a feed table comprising the steps of:

determining if said test strip possesses specified reagents;

locating the position of said reagents on said strip;

reading the infrared reflectances from the reagent positions; ~~and~~

determining if said infrared reflectances are within an acceptable predetermined range; and

determining that said test strip is misidentified in the event said infrared reflectances are outside of the acceptable predetermined range.

9. (original) The method of Claim 8, further comprising the step of aborting said method if said infrared reflectances for one or more of said reagents are not within said predetermined range.

10. (original) The method of Claim 8 wherein said reagents are leukocyte, glucose and albumin.

11. (original) The method of Claim 10 wherein said predetermined infrared reflectance range of said leukocyte reagent is from about 57.0 to about 73.0 percent infrared reflectance.

12. (original) The method of claim 10 wherein predetermined infrared reflectance range of said glucose reagent is from about 75.0 to about 90.0 percent infrared reflectance.

13. (original) The method of claim 10 wherein the predetermined infrared reflectance range of said albumin reagent is from about 60.0 to about 75.0 percent infrared reflectance.

14. (original) The method of Claim 9 wherein said test will be aborted if said test strip is

more than about 0.020" from a central location on said feed table or if said test strip is incompletely inserted by more than about 0.050".

15. (original) An automated method of reading a test strip for the analysis of one or more analyte(s) in a liquid test sample that comprises the steps of:

a) providing a test strip having at least one test field on its surface that reflects light at a specific range of wavelengths and at least two distinct marker fields on the same surface of said test strip as said test field, said marker fields reflecting light at different ranges of wavelengths from each other and from said test field in a coded sequence of ranges of wavelengths, said coded sequence correlates to information concerning identification of the test strip;

b) introducing said test strip into a strip reading device equipped with reading means for both said test field and said marker fields, said reading means comprises a light source as transmitter and a light sensitive element as receiver, said receiver being capable of differentiating between said ranges of wavelengths at which said test field and said marker fields reflect, said strip reading device also being equipped with means for correlating the coded range of infrared wavelength sequence of reflected light with preprogrammed information concerning said test strip, said correlating means being in operative communication with a receiving means, said reading device having means for moving said test strip and said receiving means relative to one another so that the reflectance of said test field and said marker fields can be individually read by said reading means;

c) allowing said ranges of wavelength values reflected by said test field and said marker fields to be individually read by said reading means;

d) allowing said reading means to communicate said coded infrared sequence of spectral reflectance values reflected from said marker fields to said correlating means and allowing said correlating means to correlate said infrared sequence of reflected range of wavelength values with said preprogrammed information concerning said test strip; and

e) allowing said reading means to communicate said reflected range of infrared wavelength values to said correlating means and allowing said correlating means to determine, for one or more of the reagents disposed on said test strip, if said reflected range of infrared

wavelength values are within a predetermined range of infrared reflectances.

16. (original) The method of claim 15 wherein said test strip is placed on a feed table.

17. (original) The method of claim 15 wherein said reagents comprise leukocyte, glucose and albumin.

18. (original) The method of claim 17 further comprising the step of aborting said method if said infrared reflectances for one or more of said reagents are not within said predetermined range.

19. (original) The method of claim 15 wherein said test will be aborted if said test strip is more than about 0.020" from a central location on said feed table or if the test strip is incompletely inserted by more than about 0.050".

20. (original) The method of claim 18 wherein the predetermined infrared reflectance range for leukocyte is from about 57.0 to about 73.0 percent infrared reflectance.

21. (original) The method of claim 18 wherein the predetermined infrared reflectance range for glucose is from about 75.0 to about 90.0 percent infrared reflectance.

22. (original) The method of claim 18 wherein the predetermined infrared reflectance range for albumin is from about 60.0 to about 75.0 percent infrared reflectance.

23. (original) The method of claim 15 wherein said range of wavelength value reflected from said test field and said marker fields are read by moving said test strip and said reading means relative to each other.

24. (original) The method of claim 15 wherein said feed table is movable in relation to said

reading means and wherein said test strip is placed on said feed table and moved relative to said reading means so that the reading means can scan the marker fields.

25. (original) The method of claim 15 wherein said reading means is capable of acquiring spatial and spectral reflectances across the length of said test strip.

26. (original) The method of claim 15 wherein said information concerning said test strip is calibration information based on the particular batch from which said test strip was obtained.

27. (original) The method of claim 15 wherein said information concerning said test strip relates to location of reactive areas, critical times, strip age and strip reactivity.

28. (original) The method of claim 15 in which said marker fields comprise bars that are substantially parallel to each other and are substantially perpendicular to the longitudinal axis of the test strip.

29. (withdrawn) A reflectance spectroscope, comprising:

a source of illumination for generating light rays;

a support member adapted to support a reagent pad, said support member having a position in which said reagent pad is illuminated by said light rays generated by said illumination source;

a reflectance detector positioned to receive light rays from said reagent pad, said reflectance detector occupying a detection area;

a housing having an aperture formed therein, said aperture being disposed between said illumination source and said reagent pad and being adapted to cause said light rays generated by said illumination source to illuminate an area of said reagent pad;

means for defining a first optical path from said illumination source to said reagent pad in which substantially all singly-reflected light rays generated by said illumination source are prevented from reaching said reagent pad, said means for defining said first optical path having a

non-planar wall comprising:

a first wall portion with a specular reflective surface disposed to reflect substantially all of said light-rays generated by said illumination source which reach said first wall portion to an area which does not include said aperture; and

a second wall portion with a specular reflective surface disposed to reflect substantially all of said light rays generated by said illumination source which reach said second wall portion to an area which does not include said aperture;

means for defining a second optical path from said reagent pad to said reflectance detector in which substantially all singly-reflected light rays from said reagent pad are prevented from reaching said reflectance detector, said means for defining said second optical path having a non-planar wall comprising:

a third wall portion with a specular reflective surface disposed to reflect substantially all of said light rays which reach said third wall portion from said reagent pad to an area which does not include said detection area; and

a fourth wall portion with a specular reflective surface disposed to reflect substantially all of said light rays which reach said fourth wall portion from said reagent pad to an area which does not include said detection area; and

means for detecting the misidentification of a diagnostic test strip by determining if said test strip possesses specified reagents, locating the position of said reagents on said test strip and reading the infrared reflectances from the reagent positions to determine if said infrared reflectances are within an acceptable predetermined infrared reflectance range.

30. (withdrawn) The reflectance spectroscope of claim 29 further comprising the step of aborting said method if said infrared reflectances for one or more of said reagents are not within said predetermined infrared reflectance range.

31. (withdrawn) The reflectance spectroscope as defined in claim 29 wherein at least one of said wall portions is substantially planar.

32. (withdrawn) The reflectance spectroscope as defined in claim 29 wherein all of said wall portions are substantially planar.

33. (withdrawn) The reflectance spectroscope as defined in claim 29 wherein said housing has a detection aperture formed therein, said detection aperture being disposed between said reagent pad and said reflectance detector.

34. (withdrawn) The reflectance spectroscope as defined in claim 32 wherein said means for defining said second optical path comprises at least one edge defined by a pair of wall portions, said edge being substantially aligned with an edge of said detection area and an edge of said detection aperture.

35. (withdrawn) The reflectance spectroscope as defined in claim 29 wherein said housing has a first detection aperture formed therein, said first detection aperture having a first edge and a second edge and being disposed between said reagent pad and said reflectance detector so that said edges of said first detection aperture are substantially aligned with a pair of edges of said detection area.

36. (withdrawn) A reflectance spectroscope as defined in claim 35 wherein said housing has a second detection aperture formed therein, said second detection aperture having a first edge and a second edge and being disposed between said first detection aperture and said reflectance detector so that said edges of said second detection aperture are substantially aligned with said pair of edges of said detection area.

37. (withdrawn) A reflectance spectroscope, comprising:

a source of illumination for generating light rays;

a support member adapted to support a reagent pad, said support member having a position in which said reagent pad is illuminated by said light rays generated by said illumination source;

a reflectance detector positioned to receive light rays from said reagent pad;

means for defining a first optical path from said illumination source to said reagent pad in which substantially all singly-reflected light rays generated by said illumination source are prevented from reaching said reagent pad; and

means for detecting the misidentification of a diagnostic test strip including a determination whether said test strip possesses specified reagents, locating the position of said reagents on said strip and reading the infrared reflectances from the reagent positions to determine if said infrared reflectances are within an acceptable predetermined infrared reflectance range.

38. (withdrawn) A reflectance spectroscope as defined in claim 37 additionally comprising a housing having an aperture formed therein, said aperture being disposed between said illumination source and said reagent pad and being adapted to cause said light rays generated by said illumination source to illuminate an area of said reagent pad.

39. (withdrawn) A reflectance spectroscope as defined in claim 38 wherein said means for defining a first optical path has a non-planar wall portion comprising:

a first wall portion with a specular reflective surface disposed to reflect substantially all of said light rays generated by said illumination source which reach said first wall portion to an area which does not include said aperture; and

a second wall portion with a specular reflective surface disposed to reflect substantially all of said light rays generated by said illumination source which reach said second wall portion to an area which does not include said aperture.

40. (withdrawn) A reflectance spectroscope as defined in claim 39 wherein at least one of said first and second wall portions is substantially planar.

41. (withdrawn) A reflectance spectroscope as defined in claim 37 additionally comprising means for defining a second optical path from said reagent pad to said reflectance detector in

which substantially all singly-reflected light rays from said reagent pad are prevented from reaching said reflectance detector.

42. (withdrawn) A reflectance spectroscope as defined in claim 41 wherein said reflectance detector occupies a detection area and wherein said reflectance spectroscope additionally comprises a housing.

43. (withdrawn) A reflectance spectroscope as defined in claim 42 wherein said means for defining a second optical path has a non-planar wall portion comprising:

a first wall portion with a specular reflective surface disposed to reflect substantially all of said light rays which reach said first wall portion from said reagent pad to an area which does not include said detection area; and

a second wall portion with a specular reflective surface disposed to reflect substantially all of said light rays which reach said second wall portion from said reagent pad to an area which does not include said detection area.

Remarks

Applicant believes that this amendment places the subject application in better condition for allowance and in so doing introduces no new issues. Therefore, entry of this Amendment, reconsideration of the application, and allowance of all claims pending herein is respectfully requested.

Claims 1-43 were originally presented in the subject application. Claims 29-43 have been withdrawn due to a previous restriction requirement. Independent claims 1 and 8 have been amended. Claims 1-28 remain in this case.

The Examiner's concerns are addressed separately below in the order raised in the outstanding Office Action. No new matter has been added.

Rejections under 35 U.S.C. §102(b)

Claims 1, 3, 8, 10, 15-17, 23-25 and 28

Claims 1, 3, 8, 10, 15-17, 23-25 and 28 stand rejected under § 102(b) as anticipated by Howard III et al., U.S. Patent No. 5,654,803. Applicant respectfully traverses this rejection, to the extent that this rejection is deemed applicable to the currently amended independent claims.

As amended, independent claim 1, from which claim 3 depends, recites "determining that the test strip is misidentified in the event the one or more reagents are outside of the acceptable predetermined range." Support for this amendment may be found in the preamble of original claim 1, and in the specification at p. 8, lines 7-21. Similarly, amended independent claim 8, from which claim 10 depends, recites "determining that said test strip is misidentified in the event said infrared reflectances are outside of the acceptable predetermined range." Support for this amendment may be found in the preamble of original claim 8, and in the specification at p. 8, lines 7-21.

Howard III et al. do not disclose using a reading from a test strip to detect the misidentification of the test strip. Instead, Howard III et al. disclose decoding the reading to determine the amount of blood on a test strip. "The decode reading is used to categorize the urine sample into one of three blood concentration categories: large blood concentration, medium blood concentration, or small blood concentration." (Howard III et al. col. 7 lines 57-

61).

Independent claim 15, from which claims 16, 17, 23-25 and 28 depend, recites in step (a) "marker fields reflecting light at different ranges of wavelengths from each other and from said test field in a coded sequence of ranges of wavelengths, said coded sequence correlates to information concerning identification of the test strip." Howard III et al. do not disclose either marker fields or a coded sequence correlating to identifying information for a test strip.

Therefore, Howard III et al. do not anticipate claims 1, 3, 8, 10, 15-17, 23-25 and 28.

Rejections under 35 U.S.C. §102(e)

Claims 1-3, 5, 7-10, 12, and 14

Claims 1-3, 5, 7-10, 12, and 14 stand rejected under § 102(e) as anticipated by Corey et al., U.S. Patent No. 6,316,264. The invention disclosed by Corey et al., which only qualifies as prior art under § 102(e), and the claimed invention were, at the time the claimed invention was made, both subject to an obligation of assignment to the Bayer Corporation. Moreover, the instant application (and Corey et al.) has a priority date after November 29, 2000, and as such, the current language of § 103(c) is applicable. Therefore, under § 103(c), the Corey et al. reference should not be cited against the instant application.

In the alternative, Applicant respectfully traverses this rejection, to the extent that this rejection is deemed applicable to the currently amended independent claims. As discussed above, Corey et al. do not disclose the characteristic of determining whether a test strip is misidentified, and therefore do not anticipate claims 1-3, 5, 7-10, 12, and 14.

Rejections under 35 U.S.C. §103(a):

Claims 4, 6, 11, 13, 18-22, and 26-27

Claims 4, 6, 11, and 13 stand rejected as unpatentable over Corey et al.; claims 18-22 stand rejected as unpatentable over Howard III et al. in view of Corey et al.; and claims 26-27 stand rejected as unpatentable over Howard III et al. in view of Corey et al., and further in view of Poto et al., U.S. Patent No. 5,728,352. Under § 103(c), as discussed above, the Corey et al. reference should not be cited against the instant application. As such, Applicant requests

withdrawal of this rejection.

In the alternative, Applicant respectfully traverses these rejections, to the extent that these rejections are deemed applicable to the currently amended independent claims. It is well settled that in order to make a prima facie case of obviousness, the cited references must teach or suggest each and every element of the claims. MPEP § 2143.03. The cited references do not teach or suggest the characteristic of amended claim 1, from which claims 4 and 6 depend, of "determining that the test strip is misidentified;" or the similar characteristic of amended claim 8, from which claims 11 and 13 depend, of "determining that said test strip is misidentified." None of the cited references discloses this characteristic.

In addition, the cited references do not teach or suggest the characteristic of independent claim 15, from which claims 18-22 and 26-27 depend, of "a coded sequence of ranges of wavelengths, said coded sequence correlates to information concerning identification of the test strip."

The Office Action does not indicate that the cited references disclose marker fields reflecting light in "a coded sequence of ranges of wavelengths, said coded sequence correlates to information concerning identification of the test strip." Instead, the Office Action simply states that Howard III et al. teach "a coded sequence of wavelengths." (Office Action p.3, *see also* pp.8,9). However, Howard III et al. do not teach or suggest either marker fields or a coded sequence of wavelengths otherwise configured for the identification of a test strip. Instead, Howard III et al. disclose reagent pads 30 on a reagent strip 22, with "each reagent and reagent pad 30 being associated with a particular test to be performed." (Howard III et al. col. 3 lines 41-46). The Howard III et al. reagent pads 30 are therefore not marker fields suitable for use as identification fields.

A separate marker field for the identification of a test strip, for example the spectral identification marker field 504 disclosed in the application, is a significant structural difference from the Howard III et al. reagent strip. Also, as claimed, the reading means must be equipped to differentiate between the wavelengths at which the marker fields and the testing fields reflect. In contrast, the Howard III et al. machine is not configured for the identification of a test strip from the spectral reflectance of marker fields on the test strip. Corey et al. and Poto et al. also do

not disclose or suggest a coded sequence of ranges of wavelengths correlating to identification information for the test strip, or a machine configured to read such a coded sequence.

The cited references also show no recognition of the problem of accurate identification of test strips, and therefore do not suggest Applicant's claimed invention. The Howard III et al. disclosure is focused on the problem of miscategorizing blood concentration in a sample. (Howard III et al. col. 1, lines 46-48, 59-63). Corey et al. state that "the present invention is directed to a dry phase test strip that ensures proper alignment of the test strip in a detection apparatus, such as a spectrophotometer." (Corey et al. col. 3 lines 61-64). The Poto et al. disclosure is limited to a specific type of test strip and test strip reader, making it unnecessary to address the issue of misidentifying a test strip. "The present invention relates generally to a disposable electronic diagnostic instrument.... The diagnostic instrument is designed and calibrated specifically for use with diagnostic test strips supplied with the OTC cholesterol test kit for measuring and displaying the cholesterol level of a tested whole blood sample." (Poto et al. col. 1 lines 11-19). Therefore, the cited references do not teach or suggest marker fields configured to reflect a coded sequence of ranges of wavelengths correlating to identification information of a test strip.

CONCLUSION

For at least each of the foregoing alternate reasons, Applicant respectfully requests reconsideration and allowance of the pending claims. Dependent claims 2-7, 8-14, and 16-28 are believed allowable for the same reasons as the independent claims from which they depend, as well as for their own additional limitations. Applicant therefore further submits that all of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot.

This application is now believed to be in condition for allowance, and such action at an early date is respectfully requested. However, if any matters remain unresolved, the Examiner is encouraged to contact the undersigned by telephone.

In the unlikely event that the transmittal letter is separated from this document and the

Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 50-0734** referencing Docket No. MSE #2620. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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Dated: August 16, 2007

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